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110TH CONGRESS
2D SESSION

H. R. 7078

To increase awareness of and research on autoimmune diseases, which are a major women's health problem, affect as many as 23.5 million Americans, and encompass more than 100 interrelated diseases, such as lupus, multiple sclerosis, rheumatoid arthritis, Sjögren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, and sarcoidosis, and for other purposes.

IN THE HOUSE OF REPRESENTATIVES

SEPTEMBER 25, 2008

Mr. KENNEDY introduced the following bill; which was referred to the Committee on Energy and Commerce

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A BILL

To increase awareness of and research on autoimmune diseases, which are a major women's health problem, affect as many as 23.5 million Americans, and encompass more than 100 interrelated diseases, such as lupus, multiple sclerosis, rheumatoid arthritis, Sjögren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, and sarcoidosis, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

SECTION 1. SHORT TITLE.

This Act may be cited as the "Prevention, Awareness, and Research of Autoimmune Diseases Act of 2008".

SEC. 2. FINDINGS.

The Congress finds as follows:

(1) The National Institutes of Health estimates that between 14 and 23.5 million Americans have an autoimmune disease and the prevalence is rising. Seventy-five percent of those afflicted are women with most cases occurring during the childbearing years.

(2) Researchers have identified more than 100 autoimmune diseases and suspect at least 40 additional disorders of having an autoimmune basis.

(3) Autoimmune diseases are chronic and can be life-threatening, ranking in the top 10 causes of death in children and women in all age groups up to 64 years of age.

(4) Early diagnosis of and commencement of treatment for autoimmune diseases can prevent or reduce serious organ damage, disability, and death. According to a study conducted by the American Autoimmune Related Diseases Association, more

than half of those with an autoimmune disease suffered for 4 years and visited 4 doctors before obtaining a diagnosis, and 44.6 percent of women were told they were chronic complainers or too concerned with their health prior to being diagnosed.

(5) A close genetic relationship exists among autoimmune diseases, explaining clustering in individuals and families as well as common pathways for disease development.

(6) The rapidly evolving field of epigenetics has shown that environmental factors can cause genes to be "turned on" or "turned off". Differing exposures to environmental factors can result in differing patterns of autoimmune expression.

(7) Frequently used immunosuppressant treatments lead to devastating long-term side effects. Those with autoimmune diseases lack effective treatments.

(8) The Institute of Medicine reports that the United States is behind other countries in research into immune system self-recognition, the process involved in autoimmune diseases.

(9) Understanding how to modulate immune system activity will benefit transplant recipients,

cancer patients, AIDS patients, and infectious disease patients.

(10) The National Institutes of Health estimates that annual direct health care costs for autoimmune disease are in the range of $100,000,000,000.

(11) Lack of awareness on the part of the public and health care professionals contributes to patients' extreme difficulty in obtaining a correct diagnosis, and lack of effective treatments. Despite the prevalence of autoimmune diseases, public awareness remains low. According to a Roper study, only 5.5 percent of Americans can even name an autoimmune disease and 29 percent incorrectly identify AIDS as an autoimmune disease. Awareness is lowest among adults ages 18 to 34, the age group most likely to develop an autoimmune disease.

(12) Examples of autoimmune diseases include lupus, multiple sclerosis, rheumatoid arthritis, Sjögren's syndrome, polymyositis, pemphigus, myasthenia gravis, Wegener's granulomatosis, psoriasis, celiac disease, autoimmune platelet disorders, scleroderma, alopecia areata, vitiligo, autoimmune thyroid disease, and sarcoidosis.

(13) Lupus can affect many parts of the body, including joints, skin, kidneys, heart, lungs, blood vessels, and brain. At least 1,500,000 Americans have a form of lupus, 9 out of 10 of these Americans are women, and 80 percent of all newly diagnosed cases of lupus are among women of childbearing age. According to a Lupus Foundation of America survey, more than half of the people with lupus suffered for 4 or more years and visited 3 or more doctors before obtaining a diagnosis of lupus. About 1 out of 5 lupus sufferers receives disability payments, costing the Government several billion dollars each year for Social Security disability benefits, lost taxes, and medical care provided through Medicare and Medicaid. The average annual cost of medical treatment for an individual with lupus is $6,000 to $10,000; for some people, medical costs may exceed several thousand dollars every month. Early diagnosis of and commencement of treatment for lupus can prevent or reduce serious organ damage, disability, and death.

(14) In multiple sclerosis (MS), the immune system attacks the protective coating around the nerves. The damage affects the brain or spinal cord and interferes with the nerve pathways, causing

muscular weakness, loss of coordination, and visual and speech problem. Multiple sclerosis is a chronic and often disabling disease of the central nervous system which often first appears in people who are 20 to 50 years of age, with lifelong physical and emotional effects. Multiple sclerosis is twice as common in women as in men. An estimated 400,000 individuals have multiple sclerosis nationally. According to the Multiple Sclerosis Society, the average annual cost of multiple sclerosis to each affected individual is approximately $57,000, and the total cost can exceed $3,000,000 over an individual's lifetime. The annual cost of treating all people who suffer from multiple sclerosis in the United States is approximately $20,000,000,000.

(15) Four million Americans suffer from Sjögren's syndrome, a serious autoimmune disease. Ninety percent of those with Sjögren's syndrome are women. Sjögren's affects all races and ethnic groups. Hallmark symptoms of Sjögren's include dry eyes and dry mouth, which can lead to corneal abrasions and blindness and loss of teeth if not recognized and treated and affect a persons' ability to eat, swallow, and digest food. Sjögren's syndrome is a systemic disease that can affect any body organ or system,

cause extreme fatigue and pain, and lead to development of non-Hodgkin's B-cell lymphoma and heart block in babies born to mothers with Sjögren's syndrome. Sjögren's syndrome is frequently misdiagnosed because of lack of recognition and physician education. According to the Sjögren's Syndrome Foundation, the average time for those who do obtain a correct diagnosis is 6.3 years after the onset of symptoms and active attempt to obtain a diagnosis.

(16) In rheumatoid arthritis, the immune system attacks the linings of the joints resulting in joint pain, stiffness, swelling, and destruction. Among the 2,100,000 people with rheumatoid arthritis in the United States, women outnumber men 3 to 1. According to the Arthritis Foundation, total direct costs of rheumatoid arthritis, including money spent on treatments, hospitalizations, medications, transportation, and specialist aids, are approximately $1,200,000,000 each year. The average medical care expenditures over the course of a rheumatoid arthritis patient's lifetime is $225,000 to $370,000.

(17) Systemic sclerosis affects approximately 240 individuals per million, and an estimated

300,000 are affected by all forms of scleroderma in the United States. Scleroderma strikes more women than men, with an overall ratio of approximately 4 to 1. Scleroderma is a chronic, often progressive autoimmune disease. The disease, which literally means "hard skin", can cause thickening and tightening of the skin, as well as fibrosis of the internal organs, including the lungs, heart, kidneys, and gastrointestinal tract. Scleroderma can be life threatening. The Scleroderma Foundation estimates the direct and indirect costs of systematic sclerosis in the United States to be $1,500,000,000, the value of lifetime earnings lost to be $300,000 per systemic sclerosis death, and direct costs at $4,731 per patient annually.

(18) Myasthenia gravis is an autoimmune neuromuscular disease which affects the skeletal muscles and is characterized by muscular weakness which is the result of a disturbance of the neuromuscular transmission. Certain muscles are more frequently involved, and these include the muscles that control eye movement, eyelids, chewing, swallowing, coughing, and facial expression. Muscles that control breathing and movement of the arms and legs may also be affected. Approximately 40 to 50

percent of individuals with myasthenia gravis experience vision problems at the time of diagnosis, and up to 90 percent experience such problems in the disease's lifetime. About 40 to 50 percent of patients experience generalized myasthenia gravis affecting the muscles of the trunk or limbs, which may result in impaired breathing. The prevalence of myasthenia gravis in the Untied States is estimated at approximately 36,000 cases. However, myasthenia gravis is probably underdiagnosed, and the prevalence is probably higher. Previous studies have shown that women are more often affected than men; however, now it seems that males over 50 are more often affected. The most common age at onset is before age 40 in women and after age 50 in men. Treatment for myasthenia gravis can cost up to $524 per month per prescription. Various surgeries can cost up to $6,000.

(19) Wegener's granulomatosis (WG) strikes 1 in every 20,000 to 30,000 people. The disease can occur at any age, although peak occurrence is in the 4th or 5th decade of life. Males and females are affected equally. Wegener's granulomatosis is a rare form of vasculitis, a disease characterized by inflammation of blood vessel walls which can damage vital

organs by restricting blood flow. Wegener's granulomatosis primarily affects the respiratory tract (sinus, nose, trachea, and lungs) and the kidneys and may involve the joints, eyes, and skin. According to the Wegener's Granulomatosus Association, patients experience a 26 percent reduction in income within the first year of diagnosis, or $9,700,000 per year in lost income total for all Wegener's patients. A 1998 survey of Wegener's patients showed costs of $33,517 per patient per year.

(20) In immune thrombocytopenic purpura (ITP), the body mounts an autoimmune attack against platelets, particles in the blood essential for clotting. People with immune thrombocytopenic purpura are prone to spontaneous hemorrhages, potentially in the brain and other vital organs. According to the Platelet Disorders Support Association, treating immune thrombocytopenic purpura costs from several thousand to hundreds of thousands of dollars per year, depending on the severity of the case and response to treatments. Immune thrombocytopenic purpura is a diagnosis of exclusion. Many other diseases and conditions present with low platelets and can be confused with immune thrombocytopenic purpura.

(21) According to the National Alopecia Areata Foundation, over 4,500,000 Americans have alopecia areata, alopecia totalis, or alopecia universalis, or 1.7 percent of any given population. While children are affected most frequently, alopecia areata occurs in all ages and ethnicities and in males and females. Alopecia areata results in hair loss, with many people losing all hair over their entire body, including eyebrows and eyelashes and the hair on their head. This leads to loss of self-esteem and filtering protection from the elements and cold. Denting and stripping of nails can also occur along with complete nail loss. Since no approved treatments exist for alopecia areata, insurance companies fail to recognize its seriousness and do not cover treatments that could affect the disease's course. Treatments are often paid for by patients or not administered. Diagnosis is difficult because of lack of knowledge, especially among pediatricians and general practitioners who would refer patients to specialists. The International Pemphigus Foundation estimates the incidence of pemphigus and pemphigoid as between 1 and 5 people per hundred thousand. These diseases affect all races and ethnic groups. Pemphigus and pemphigoid are a group of chronic, rare autoimmune blistering

diseases of the skin or mucous membranes. They are characterized by painful, burn-like blisters or lesions covering much of the body that do not heal, and they can cause serious infection, difficulty swallowing, and, with cicatricial pemphigoid (CP), blindness. If untreated, pemphigus is usually fatal.

(22) Polymyositis is an autoimmune disease that causes inflammation of the small and medium-sized arteries and leads to problems in the muscles, joints, intestines, nerves, kidney, and skin. Myositis is a neuromuscular autoimmune disease affecting about 50,000 Americans. Because it is rare and not easily detectable, individuals with myositis are often misdiagnosed. It is common for those with myositis to go either undiagnosed or misdiagnosed for several years before getting a correct diagnosis. The efficacy of treatment is diminished by delayed diagnoses and the resulting medications required and costs incurred are substantially higher.

(23) More than 5,000,000 people in the United States have been diagnosed with psoriasis or psoriatic arthritis, including children. Psoriasis is a lifelong skin disease that occurs when faulty signals in the immune system cause skin cells to regenerate too quickly. Extra skin cells build up on the skin's sur-

face forming red, flaky, scaly lesions that can itch, crack, bleed, and be extremely painful. Psoriasis generally appears on the joints, limbs, and scalp, but it can appear anywhere, covering some people from head to toe. The National Psoriasis Foundation estimates the cost of psoriasis care in the United States ranges from $650,000,000 a year to $4,300,000,000 a year. A recent study estimates that Americans with psoriasis lose about 56 million hours of work and spend $2 to $3 billion to treat the disease each year.

(24) Sarcoidosis results in small growths of blood vessels, cells, and connective tissue and leads to problems in the skin, lungs, eyes, joints, and muscles. Sarcoidosis is a disease due to inflammation that can attack any organ in the body in any location. The disease is characterized by the presence of granulomas, small areas of inflamed cells. They can be either inside the body or on the body's exterior, appearing as sores on the face or shins. Sarcoidosis is most frequently found in the lungs. There are about 25,000 cases of sarcoidosis in the United States. African-Americans have a higher risk for sarcoidosis than do other Americans. However, the disease occurs in every race in the United States and

throughout the world, including in individuals of European ancestry. Sarcoidosis occurs predominantly between the ages of 20 and 40 years of age.

(25) Vitiligo affects 1 to 2 percent of the population, or about 3 to 6 million Americans, and affects every nationality, race, and gender equally. Vitiligo is an autoimmune disease in which the immune system mistakenly attacks the pigment cells in the skin. It appears as milky white patches and can occur anywhere on the body. Usually progressive, it can have a devastating impact on a patient's mental state, especially in those with darker skin. Cost varies by treatment. Treatment can cost up to $150 a month for topical medications, $2,000 to $3,000 for a home unit for phototherapy, and up to $30 per doctor's office visit 2 to 3 times per week. Laser treatments can cost $100 to $200 per treatment per area. Diagnosis can be extremely difficult, as loss of pigment occurs in several other conditions, and physician education is lacking. It can take several months or trips to several different dermatologists for a definitive diagnosis.

SEC. 3. RESEARCH ON ENVIRONMENTAL TRIGGERS OF AUTOIMMUNE DISEASES.

Subpart 12 of part C of title IV of the Public Health Service Act (42 U.S.C. 285l et seq.) is amended by adding at the end the following:

"RESEARCH ON ENVIRONMENTAL TRIGGERS OF AUTOIMMUNE DISEASES

"SEC. 463C. (a) The Secretary, acting through the Director of the Institute and in collaboration with the directors of such other national research institutes as the Secretary deems appropriate, shall award not less than 2 grants to eligible entities for the conduct or support of research on environmental triggers, such as heavy metals, phalates, and pharmaceuticals, that can cause the initiation of autoimmune diseases in genetically predisposed individuals.

"(b) Each grant under this section shall be for a period of 5 years.

"(c) In this section, the term 'eligible entity' means—

"(1) a nonprofit organization;

"(2) a consumer group; or

"(3) an institution of higher education (as defined in section 101 of the Higher Education Act of 1965); or

"(4) a Federal, State, or local agency.".

SEC. 4. GRANTS TO INCREASE AWARENESS OF AUTOIMMUNE DISEASES.

(a) PURPOSE.—The purpose of this section is to increase awareness of autoimmune diseases in order to provide to the public a more complete understanding of these diseases, which affect 5 to 10 percent of the people in the United States.

(b) AMENDMENTS.—Title III of the Public Health Service Act (42 U.S.C. 241 et seq.) is amended by inserting after section 317S the following:

"SEC. 317T. GRANTS TO INCREASE AWARENESS OF AUTOIMMUNE DISEASES.

"(a) GRANTS.—The Secretary, acting through the Director of the Centers for Disease Control and Prevention, shall award grants to eligible entities to conduct public and professional awareness activities regarding autoimmune diseases.

"(b) USE OF FUNDS.—In conducting public and professional awareness activities with a grant under this section, an eligible entity may do any of the following:

"(1) Promote increased awareness of early intervention and treatment so as to significantly improve the quality of life for people with autoimmune diseases.

"(2) Target minority communities that may be underserved or disproportionately affected by autoimmune diseases.

"(3) Target women (who are disproportionately affected by autoimmune diseases) so as to help reduce the amount of time taken for correct diagnosis of such diseases, which often takes more than 1 year.

"(e) ELIGIBLE ENTITY.—For purposes of this section, the term 'eligible entity' means a nonprofit organization, a consumer group, an institution of higher education (as defined in section 101 of the Higher Education Act of 1965), a Federal, State, or local governmental agency, or a media organization.

"(d) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $18,000,000 for each of fiscal years 2009 and 2010.".

SEC. 5. GRANTS FOR EDUCATION ON RELATIONSHIP BETWEEN AUTOIMMUNE DISEASES AND MENTAL ILLNESSES.

Title III of the Public Health Service Act (42 U.S.C. 241 et seq.), as amended by section 4, is amended by inserting after section 317T the following:

"SEC. 317U. GRANTS FOR EDUCATION ON RELATIONSHIP BETWEEN AUTOIMMUNE DISEASES AND MENTAL ILLNESSES.

"(a) GRANTS.—The Secretary, acting through the Administrator of the Health Resources and Services Administration, shall award grants to eligible entities for the education of health care providers on potential links between autoimmune diseases and cognitive and mood disorders, such as depression.

"(b) ELIGIBLE ENTITY.—For purposes of this section, the term 'eligible entity' means a nonprofit organization, a consumer group, an institution of higher education (as defined in section 101 of the Higher Education Act of 1965), a Federal, State, or local governmental agency, or a media organization.

"(c) AUTHORIZATION OF APPROPRIATIONS.—There is authorized to be appropriated to carry out this section $5,000,000 for each of fiscal years 2009 and 2010.".

SEC. 6. LOAN REPAYMENT PROGRAM REGARDING PHYSICIAN RESEARCH ON AUTOIMMUNE DISEASES.

Title IV of the Public Health Service Act (42 U.S.C. 281 et seq.) is amended—

(1) by redesignating the second section 487F as section 487G; and

(2) by inserting after section 487G (as so redesignated) the following:

"SEC. 487H. LOAN REPAYMENT PROGRAM REGARDING PHYSICIAN RESEARCH ON AUTOIMMUNE DISEASES.

"(a) ESTABLISHMENT.—To the extent and in the amounts provided in advance in appropriations Acts, the Secretary, acting through the Administrator of the Health Resources and Services Administration, shall establish a program to enter into contracts with qualified physicians under which such qualified physicians agree to conduct research for a period of at least 3 years regarding autoimmune diseases in consideration of the Federal Government agreeing to repay, for each year of service conducting such research, not more than $35,000 of the principal and interest of the educational loans of such qualified physicians.

"(b) APPLICATION OF PROVISIONS.—Except as inconsistent with this section, the provisions of sections 338B, 338C, and 338E shall apply to the program established under this section to the same extent and in the same manner as such provisions apply to the National Health Service Corps Loan Repayment Program established in subpart III of part D of title III.

"(c) QUALIFIED PHYSICIAN.—For purposes of this section, the term 'qualified physician' means any individual who has received, or will have received by the time of the research to be conducted under this section, a de-

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gree of doctor of medicine or its equivalent and is licensed to practice medicine in the United States.".

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